Veterinary Medicines Directorate

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Post Authorisation Assessments

Dectomax 10mg/ml Solution for Injection for Cattle and Sheep

Vm 00879/4199

•	22 June 2023	Minor changes to analytical test procedure of assay and related substance. Minor changes to analytical test procedure of BHA assay. Minor changes to analytical test procedure of determination of colour test.
•	29 March 2022	Change in the name of the manufacturer of the finished product.
•	16 February 2022	Change in distributor details from distributors Pfizer Ltd, Ramsgate Road, Sandwich, Kent, CT139NJ and UniDrug Distribution Group Ltd, Amber Park, Berristow Lane, South Normanton, Derbyshire, DE55 2FH to Elanco UK AH Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	05 October 2021	Change to part of the (primary) packaging material not in contact with the finished product formulation.
•	23 December 2020	Change of MAH, from Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL to Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	26 June 2020	Change in the name of the manufacturer of the finished product.
•	16 April 2020	Addition of a site where batch control/testing takes place. Deletion of manufacturing site of the finished product where batch control takes place.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	19 February 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	20 July 2016	Minor change in the manufacturing process of the finished product. Deletion of a non-significant in- process test applied during the manufacture of the finished product.
•	28 February 2014	Changes to the SPC and product literature following an EU Directive.
•	12 September 2013	Change of packaging size – vial size from 200ml to 250ml
•	20 June 2013	Addition of manufacturing site for all of the manufacturing process of the finished product
•	13 November 2012	Addition of two secondary packaging sites

•	04 September 2012	Addition of alternative test performed on the finished product
•	29 August 2012	Addition of alternative test performed on the finished product
•	16 August 2012	Deletion of in-process test performed during manufacture of the finished product
•	22 December 2010	Change of MAH
•	10 August 2010	Change of address of manufacturing site of the finished product
•	10 November 2009	Change to withdrawal period for meat from sheep from 70 days to 63 days
•	19 March 2008	Corrections to the SPC and product Literature
•	14 December 2007	Change of legal category from PML to POM-VPS Changes to the SPC and Product Literature to bring in line with new legislation
•	09 May 2007	Renewal
•	28 July 2005	Minor changes to the Product Literature to include new site of manufacture
•	24 June 2005	Addition of a distributor
•	25 February 2005	Change of name of manufacturing site of assembly
•	11 November 2004	Change of batch size of the finished product Change to stability conditions Addition of a site of manufacture of the finished product
•	28 January 2004	Change of withdrawal period for meat from sheep from 56 days to 70 days
•	09 January 2004	Change in test procedure for excipients
•	26 March 2001	Renewal
•	16 September 1999	Change to indications regarding efficacy against two parasites
•	23 July 1998	Addition of indication for Mange Mites Change of withdrawal period for meat from sheep to 56 days
•	12 March 1998	Change of indications
•	29 September 1997	Change of indications
•	26 September 1996	Change of indications
•	05 August 1996	Additional formulation
•	11 March 1996	Change of shelf life
•	15 January 1996	Change of safety warnings
•	20 September 1995	Change of safety warnings
•	31 July 1995	Change of legal category
•	18 April 1995	Change to indications